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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,232

11/20/2003

Mark J. Rosenfeld

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08/22/2006

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EXAMINER

ZHANG, NANCY L

ART UNIT PAPER NUMBER

1614

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,232

Applicant(s)

ROSENFELD ET AL.

Examiner

Nancy L. Zhang

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 91-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 and 91-104 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

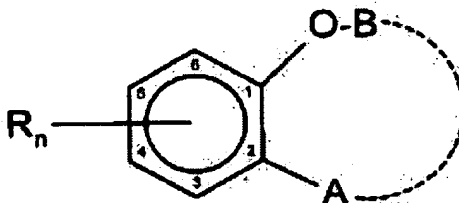
DETAILED ACTION

Applicant's election of Group I, claims 1-15 in the reply filed on 3/2/2006 is acknowledged. In the reply, the applicant also amended the case by submitting new claims 91-104. Upon a closer review of claims 1-15 and claims 91-104, the examiner has decided that a new restriction requirement is necessary.

Election/Restrictions

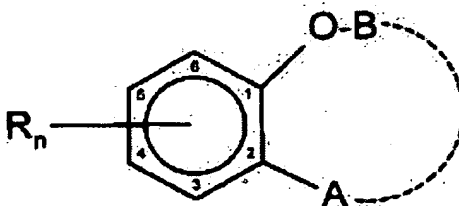
Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 14-15, 91-93 and 103-104, drawn to a process of using a product of compositions defined as:



classified in class 514, subclass 230.5 and 909. If this group is elected, the below summarized species election is also required.

- II. Claims 5-13 and 94-102, drawn to a process of making a product of compositions defined as:



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classified in class 514, subclass 230.5 and 909. If this group is elected, the below summarized species election is also required.

The inventions are distinct, each from the other because of the following reasons:

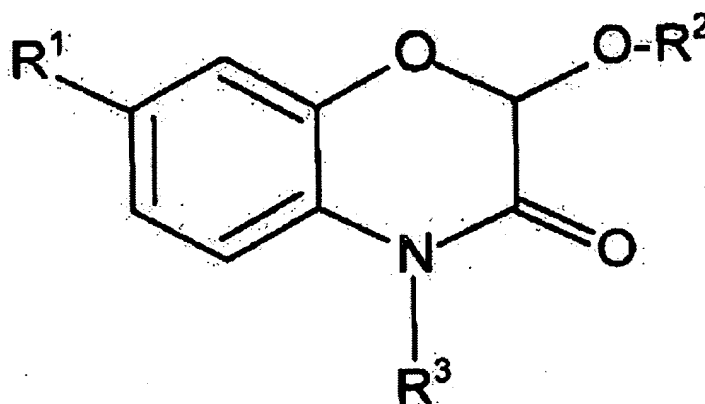
Inventions in Group II and Group I are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). The product is not allowable because it is known in the art and it can be made by a process that is materially different from the process of making as claimed in Group II. For example, chemical compositions as defined above can be a compound of 6-methoxy-2(3H)-benzoxazolinone which can be obtained by organic synthesis as disclosed by Allen et al. (J. Org. Chem., 36, 2004 (1971)).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election for Group I

Invention in Group I contains claims directed to the following patentably distinct species.

(I-A) The product used in the invention is a chemical composition defined as:



Wherein "R¹" is selected from the group consisting of H and OCH₃;

Wherein "R²" is selected from the group consisting of H and Glucose (as a glucoside);

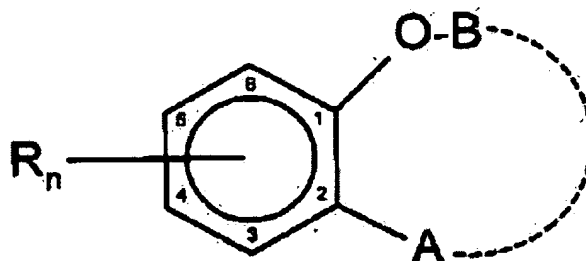
Wherein "R³" is selected from the group consisting of H, OH, and OCH₃; or

pharmaceutically acceptable salts thereof.

The applicant is required to specify a compound.

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(I-B) The product used in the invention is a chemical composition defined as:

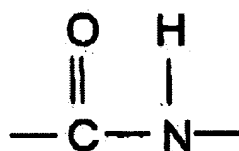


Wherein "R" represents C_1 - C_4 alkoxy, with the provision the R is in the 4 or 5 ring position;

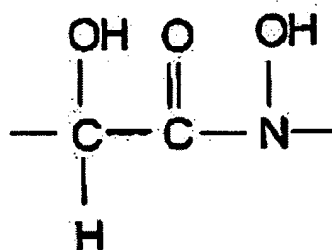
Wherein "n" represents one of the integers 0, 1 or 2;

Wherein "B" represents H and "A" represents $-OH$, $-NH_2$ or $NHCR'$, where R' denotes C_1 - C_4 alkyl;

and "B A" represents



or



or pharmaceutically acceptable salts thereof.

that is not a compound of (I-A). The applicant is required to specify a compound.

In addition, further species election is required as follows for the amount of product used in the claimed process:

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(I-a) a daily dosage of 15 mg

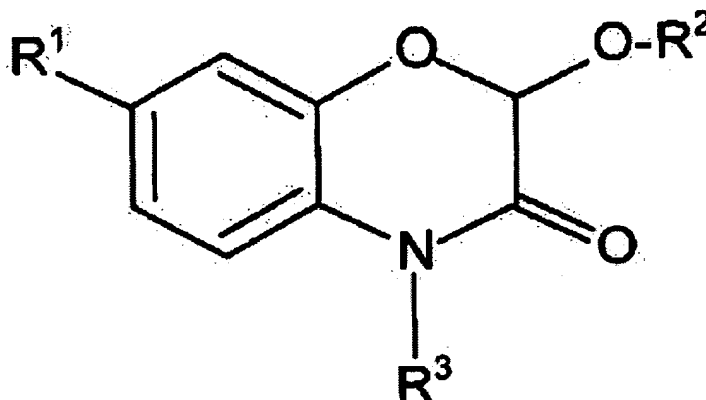
(I-b) a daily dosage of between about 5 mcg and about 60 mg that is not (I-a).

(I-c) any amount that is not (I-a) or (I-b).

Species Election for Group II

Invention in Group II contains claims directed to the following patentably distinct species.

(II-A) The product made in the invention is a chemical composition defined as:



Wherein "R¹" is selected from the group consisting of H and OCH₃;

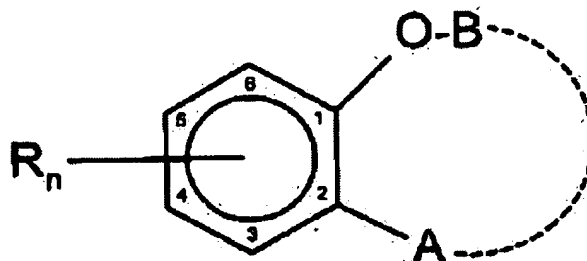
Wherein "R²" is selected from the group consisting of H and Glucose (as a glucoside);

Wherein "R³" is selected from the group consisting of H, OH, and OCH₃; or
pharmaceutically acceptable salts thereof.

The applicant is required to specify a compound.

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(II-B) The product made in the invention is a chemical composition defined as:

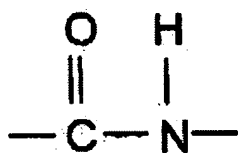


Wherein "R" represents C₁-C₄ alkoxy, with the provision the R is in the 4 or 5 ring position;

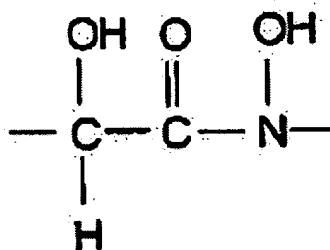
Wherein "n" represents one of the integers 0, 1 or 2;

Wherein "B" represents H and "A" represents -OH, -NH₂ or NHCR', where R' denotes C₁-C₄ alkyl;

and "B A" represents



or



or pharmaceutically acceptable salts thereof.

that is not a compound of (II-A). The applicant is required to specify a compound.

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The above listed species are independent or distinct because different compounds are included in the composition. Different compounds have different structures, chemistry, binding activities and biological effects. The therapeutically effects of different compounds thus differ when being administered for treatment. Searching for one compound is not likely to result in finding art pertinent to the other compounds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

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Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NLZ 8/9/06

NLZ

Ardin H. Marschel 8/17/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER